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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/660,022

09/12/2000

Antonio Lopez Cabrera

U-012473-1

5837

7590

04/23/2002

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EXAMINER

WARE, TODD

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 04/23/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/660,022

Applicant(s)

CABRERA ET AL

Examiner

Todd D War

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt of request for extension of time and amendment filed 1-28-02 is acknowledged. Claim 1 has been canceled, claims 2-15 and 19-23 have been amended and new claim 25 has been added. Claims 2-25 are pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Recitation of "the same release profile of the benzimidazole" or "a different release profile of the benzimidazole" in claims 21-22, respectively, is indefinite. The release profile of the benzimidazole is not provided in the claims from which these depend and these claims are to pellets that each have the benzimidazole. How would a pellet have the same or different release profile as itself?

Claim 23 requires a ratio, but to recite whether the ratio is in weight percent or volume percent and is therefore indefinite.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 2-21, 25 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Sachs et al (5,945,124; hereafter '124).

'124 discloses pantoprazole pellets having a core, a layer comprising HPMC and pantoprazole, another layer that is a release-slowing layer applied over the HPMC/pantoprazole layer, and an enteric coating applied thereon (abstract; C 3, L 61-C 4, 14; C 4, L 20-23; C 4, L 48-C 6, L 9; example 3; claims). The release-slowing layer comprises ethylcellulose and HPMC.

5. Claims 2-21, 25 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Sachs et al (5,945,124; hereafter '124) or Sachs et al (6,068,856; hereafter '856).

'124 and '856 disclose pantoprazole pellets having a core, a layer comprising HPMC and pantoprazole, another layer that is a release-slowing layer applied over the HPMC/pantoprazole layer, and an enteric coating applied thereon (abstract; C 3, L 61-C 4, 14; C 4, L 20-23; C 4, L 48-C 6, L 9; example 3; claims).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sachs et al (5,945,124; hereafter '124) or Sachs et al (6,068,856; hereafter '856).

'124 teaches pantoprazole pellets having a core, a layer comprising HPMC and pantoprazole, another layer that is a release-slowing layer applied over the HPMC/pantoprazole layer, and an enteric coating applied thereon (abstract; C 3, L 61-C4, 14; C4, L 20-23; C 4, L 48-C 6, L 9; example 3; claims). The release-slowing layer comprises ethylcellulose and HPMC. Plasticizers and other excipients are also contemplated. Furthermore, varying the thickness (therefore the amount) controls the release rate. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to provide mixtures of pellets having different release profiles in an effort to provide quicker release of the active agent while also providing prolonged release of the active agent.

8. Claims 2-21, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sachs et al (5,945,124; hereafter '124) in view of Paradissis et al (5,445,829; hereafter '829) or Sachs et al (6,068,856; hereafter '856) in view of Paradissis et al (5,445,829; hereafter '829).

'124 and '856 are relied upon for all that they teach as stated previously. Neither '124 nor '856 teaches the limitation where the pellets have different release profiles of the active agents.

'829 is relied upon for teaching capsules comprising fast and slow release layered pellets to provide both a quicker onset of action and a prolonged duration of action.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine the teachings of '829 with '124 or '856 with the expectation of providing a particular dose release profile that provides both a quick onset of action and a prolonged duration of action.

Response to Arguments

9. Applicant's arguments filed 1-28-02 have been fully considered but they are not persuasive. Since applicants' arguments are based upon the same principle, the response to arguments is applied concurrently for the responses to the different rejections.

Applicants argue that since the art requires an alkaline core or nucleus, they do not teach or disclose an inert core or nucleus as required in the instant claims. This argument is not found persuasive as the art meets the definition of an inert core or nucleus as defined in the instant specification on page 6, line 19-22 of the instant specification which states, "The inert nucleus(a) is a pharmaceutically inert substance in relation to the active ingredient, that is to say, it does not react with the active ingredient in the conditions used in such a way that there is decomposition thereof, and it may be composed of a sugar, for example, saccharose, starch and mixtures thereof." The core

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or nucleus of the art meets this definition. The actives of the art are acid labile and decompose in an acid environment, not alkaline.

Statements that the active the art must be in an alkaline salt form and is present in an alkaline tablet or pellet form are not persuasive as the claims only require an acid labile benzimidazole compound and these compounds meet that limitation.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on 8:30 AM - 5 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.


Gollamudi S. Kishore, PhD
Primary Examiner
Group 1500

tw
April 21, 2002